

### **REMARKS**

This Amendment is responsive to the final Office Action dated June 20, 2006, and is being submitted with a Request for Continued Examination (RCE) filing. This Amendment constitutes the required submission for the RCE. Applicants have amended claims 12, 13 and 22, and added new claim 33. Claims 12-33 are now pending.

As a preliminary matter, Applicants note confusion concerning the rejection of claims 14-21 in the final Office Action. For claims 14-21, the Examiner simply stated that “these claims are rejected in the same manner as set forth in Office Action dated March 21, 2004.” However, claims 14-21 are dependent upon claim 13, which was rejected based on new grounds in the final Office Action. Therefore, the rejections advanced in the Office Action dated March 21, 2004 with respect to dependent claims 14-21 are clearly inapplicable insofar as these claims are dependent upon claim 13, for which the Examiner withdrew the grounds of rejection advanced in the Office Action dated March 21, 2004, and asserted new grounds of rejection.

In the final Office Action, the Examiner rejected claims 12-32 under 35 U.S.C. 103(a) as being unpatentable over Mangram et al. (Guideline for prevention of surgical site infection) (“Mangram”) in view of Ormond-Walshe, Sarah (Computerized databases in infection control) (Ormond-Walshe) and further in view of Jacober (US 6,662,081). Applicants respectfully traverse the rejections to the extent such rejections may be considered applicable to the amended claims. The applied references fail to disclose or suggest the inventions defined by Applicants’ claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Applicants’ pending claims concern computer-implemented techniques and systems for managing risks of surgical site infection in a surgical procedure. In particular, claim 12 recites a computer-implemented system for managing the risk or occurrence of surgical site infection incident to a surgical procedure. The computer-implemented system of claim 12 comprises software that identifies a plurality of stages of operative care associated with the surgical procedure, including at least a preoperative stage, an intraoperative stage and a postoperative stage. The software also identifies one or more points-of-care within each identified stage of operative care associated with the surgical procedure, and for each point-of-care associated with the surgical procedure, identifies one or a plurality of health care delivery practices associated

with the surgical procedure that pose a source of measurable risk of surgical site infection, and identifies one or more compliance indicators associated with the surgical procedure for one or a plurality of health care practices associated with the surgical procedure within each point-of-care associated with the surgical procedure whereby there is provided the ability to monitor the compliance indicators. For each of the compliance indicators, the software generates a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby align the health care delivery practices associated with the surgical procedure into rule compliance and to provide a perioperative process map of delivery practices spanning the plurality of stages of operative care associated with the surgical procedure to thereby manage the risk or occurrence of surgical site infection incident to the surgical procedure.

Claim 13 recites a system for managing the risk or occurrence of surgical site infection incident to a surgical procedure, the system comprising a perioperative process map of practices for the delivery of the surgical procedure, the map comprising a plurality of health care delivery practices associated with the surgical procedure and one or more indicators of compliance with the one or more health care practices, and means for monitoring the compliance indicators to achieve a desired level of management of the risk of surgical site infection for the surgical procedure, wherein the means for monitoring the compliance indicators generates a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure.

Claim 22 recites a computer-implemented method for managing risks of surgical site infection incident to a surgical procedure, the method comprising evaluating a practice associated with the surgical procedure that poses an infection risk during a stage of the surgical procedure, storing data indicative of the practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedure, and identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage risks of surgical site infection incident to the surgical procedure.

In the Office Action, the Examiner cited Mangram as teaching techniques for managing risks of surgical site infection in a surgical procedure. The Examiner recognized that Mangram fails to suggest a computer-implemented system for managing such risks, but cited

Ormond-Walshe as teaching the use of computerized databases in the medical field. The Examiner argued that a person of ordinary skill in the art would have been motivated to implement the computerized databases of Ormond-Walshe to manage the risks of surgical site infection taught by Mangram.

At this point in the analysis, the Examiner recognized that the combination of Mangram and Ormond-Walshe still fails to disclose or suggest generating a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule (claims 12 and 13) or identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice (claim 22). However, the Examiner cited Jacober as disclosing the setting of flags in the context of medication delivery and concluded that a person of ordinary skill in the art would have been motivated to combine the teaching of Mangram, Ormond-Walshe and Jacober to arrive at the features recited in Applicants' claims.

Applicants respectfully traverse the rejections to the extent such rejections may be considered applicable to the amended claims. Nothing in Jacober or any of the applied references discloses or suggests generating a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13) or identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claim 22). Moreover, a person of ordinary skill in the art would not have been motivated to implement the techniques or devices of Jacober with the teaching of Mangram or Ormond-Walshe as these teaching are totally unrelated and concern totally different areas of endeavor.

The Jacober reference describes a medication regimen container and system. In particular, Jacober describes a medication dispensing unit that can be programmed to signal proper medication dosages to a user, and the times of such dosages. Nothing in Jacober discloses or suggests the generation of a flag when a given health care practice associated with a surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13) or the identification of when the data

indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claim 22). Indeed, Jacober does not even relate to surgical procedures, whatsoever. The current claim amendments should make these distinctions more apparent insofar as the current claim amendments clarify that the generation of the flag or the identification of the data are associated with a surgical procedure to thereby manage the risk of surgical site infection incident to the surgical procedure.

Applicants also dispute the Examiner's conclusions that a person of ordinary skill in the art would have been motivated to modify the teachings of Mangram and Ormond-Walshe in view of Jacober to arrive at a computerized system for managing surgical site infection incident to the surgical procedure by generating flags when a given health care practice associated with the surgical procedure is not in compliance with a rule.

Indeed, the teaching of Jacober is completely unrelated to that of Mangram and Ormond-Walshe. Accordingly, a person of ordinary skill in the art would have found no reason to modify the teachings of Mangram and Ormond-Walshe in view of Jacober. To be sure, Jacober concerns a medical regimen container for managing the dispense of medication, and has no relevance in the field of surgical procedures whatsoever, much less management of risks of surgical site infection incident to the surgical procedure. Thus, even if Jacober could be reasonably construed as generating a flag, the flag of Jacober relates to the dispensation of medication from a programmable container, and has no relevance to a surgical procedure nor the management of risks of surgical site infection incident to the surgical procedure.

Furthermore, Applicants also dispute the Examiner's more basic conclusion that the teaching of Mangram and Ormond-Walshe to implement compliance indicators associated with the surgical procedure for one or a plurality of health care practices associated with the surgical procedure. While Mangram may provide a manual guideline for prevention of surgical site infection, this reference lacks any suggestion of compliance indicators associated with the surgical procedure for one or a plurality of health care practices associated with the surgical procedure whereby there is provided the ability to monitor the compliance indicators. Moreover, the vague teaching of Ormond-Walshe concerning the use of computerized databases would have provided no additional insight to a person of ordinary skill in the art regarding the

implementation of compliance indicators associated with the surgical procedure. In particular, the broad general discussion of computerized databases for use by infection nurses, per Ormond-Walshe, provides no insight to the specific implementation of compliance indicators associated with the surgical procedure, as recited e.g., in claims 12 and 13.

In short, Applicants dispute the Examiner's conclusion that a person of ordinary skill in the art would have been motivated to combine the teaching of Mangram and Ormond-Walshe to implement compliance indicators. Neither Mangram nor Ormond-Walshe (either alone or in combination) disclose or suggests this feature.

In addition, neither Jacober nor any of the applied references discloses or suggests computerized generation of a flag or identification of data associated with a surgical procedure to thereby manage the risk of surgical site infection incident to the surgical procedure. To the extent that Jacober teaches the generation of any type of flag, the flag of Jacober relates to the dispensing of medication from a programmable container, and has no relevance to a surgical procedure nor the management of risks of surgical site infection incident to the surgical procedure. Furthermore, a person of ordinary skill in the art would have found no reason to modify the teachings of Mangram and Ormond-Walshe in view of Jacober, as these teachings concern totally different fields of endeavor. Indeed, the dispensing of medication from a programmable container, per Jacober, is not reasonably pertinent to the teachings of Mangram concerning prevention of surgical site infection nor the teaching of Ormond-Walshe concerning computerized databases for infection control. For each of these reasons, the current rejections must be withdrawn.

In view of the current claim amendments and foregoing comments, Applicants respectfully request the Examiner's reconsideration and prompt allowance of all pending claims. In view of the distinctions addressed above between the current claims and the applied prior art, Applicants reserve further comment at this time on any other features of the independent or dependent claims. However, Applicants do not necessarily acquiesce in any of the rejections or the Examiner interpretations of the applied references. Applicants reserve the right to present additional arguments with respect to any of the independent or dependent claims.

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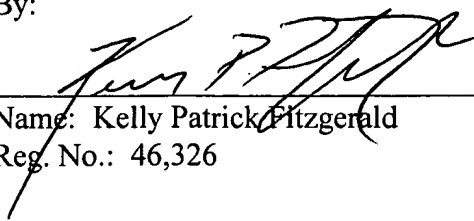
Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

August 21, 2006

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